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FEB 20 2009

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
PiGalileo Total Hip Replacement (THR) V3.0

Contact Person and Address
Gino Rouss
Regulatory Affairs Manager
Smith & Nephew Orthopaedics
1450 Brooks Road
Memphis, TN 38116
(901) 399-6707

Date of Summary: 11/25/2008

Name of Device: Smith & Nephew PiGalileo Total Hip Replacement (THR) Software Application V3.0
Common Name: PiGalileo Total Hip Replacement (THR) V3.0

Device Description
The PiGalileo Navigation System is a software-controlled electromechanical stereotaxic device for computer aided navigation of PiGalileo surgical instruments with the purpose of assisting the surgeon in optimally positioning knee and hip prostheses during total knee and hip arthroplasties.

The PiGalileo THR V3.0 software application is a surgical technique for computer assisted navigation that leverages PiGalileo Total Hip Replacement (THR) instruments as well as a number of non-navigated hip instruments with the intent to optimally position hip prostheses during total joint arthroplasty.

Device Classification
21 CFR 882.4560 Stereotaxic Instrument – Class II

Indications for Use
The Smith & Nephew PiGalileo Total Hip Replacement (THR) V3.0 is intended to be used in computer assisted orthopedic surgery to aid the surgeon with bone cuts and implant positioning during joint replacement. It provides information to the surgeon that is used to place surgical instruments during surgery utilizing anatomical landmarks and other data specifically obtained intra-operatively (e.g. hip center, pelvic plane etc.).

Examples of surgical procedures include but are not limited to:

- Primary total hip replacement
- Revision hip surgery
- Minimally invasive hip arthroplasty

Substantial Equivalence Information
The overall software design and the instruments used with Smith & Nephew PiGalileo Total Hip Replacement (THR) V3.0 software application are substantially equivalent to the previously cleared application listed below:

Manufacturer	Description	510(k)	Clearance Date
PLUS Orthopedics AG	PiGalileo Total Hip Replacement (THR) System (THR V2.5 Software)	K070731	7/31/07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2009

Smith & Nephew, Inc.
% Mr. Gino J. Rouss, MS
Manager, Regulatory Affairs
1450 Brooks Road
Memphis, Tennessee 38116

Re: K083565
Trade/Device Name: PiGalileo Total Hip Replacement (THR) Software Application V3.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: January 21, 2009
Received: January 22, 2009

Dear Mr. Rouss:

This letter corrects our substantially equivalent letter dated February 20, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: PiGalileo Total Hip Replacement (THR) Software Application V3.0

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Prescription Use X AND/OR Over-The-Counter Use ______

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature] for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083565